REMARKS

In an Official Action dated November 17, 2004, the Examiner rejected claims 1-4, 6-10, 16, 19, 20, 22, 24, 25, 28, 31-33 and 48-40. In addition, the Examiner withdrew claims 5, 13, 23, 27, 30 and 35-37 as drawn to non-elected species. Applicants request that the Examiner reconsider the rejection of claims 1-4, 6-10, 16, 19, 20, 22, 24, 25, 28, 31-33 and 48-40 and the withdrawal of claims 5, 13, 23, 27, 30 and 35-37 in light of the following discussion.

Withdrawal of Claims 5, 13, 23, 27, 30 and 35-37

In a Response dated September 27, 2004, Applicants elected the first class of inventions identified by the Examiner, namely the apparatus in claims 1-40. In addition, Applicants elected Species J, which is the embodiment illustrated in Figs. 12-16, and identified claims 1-10, 13, 16, 17, 19, 20, 22-25, 27, 28, 30-33 and 35-40 as the claims that read on Species J. However, in the Official Action the Examiner withdrew claims 5, 13, 23, 27, 30 and 35-37 without explanation.

Claims 5 and 27

Claims 5 and 27 recite "one or more stops that impede continued rearward displacement of the first sharpened tip . . . as the needle is moved to the shielded position." Referring to Figs. 15 and 16, the application shows a pair of guide arms that cooperate with a pair of lockout windows to retain the needle in the retracted

position, as shown in Fig. 16. These features are the same as the guide arms 28 and lockout windows 39 illustrated and described in the embodiment in Figs. 1-11. Since the features in claims 5 and 27 are included in the elected species, claims 5 and 27 should not have been withdrawn from consideration.

Claims 13 and 35

Claims 13 and 35 recite that the fluid flow controller comprises a mid seal within the cartridge and an elongated fluid passage in the side wall of the cartridge. These features are shown in Figs. 12-16 and described on page 24 line 14 - page 25 line 14 in the description of mid seal 170 and fluid passage 160. Since the features in claims 13 and 35 are included in the elected species, claims 13 and 35 should not have been withdrawn from consideration.

Claim 23

Claim 23 recites a needle carrier fixed to the needle. Figures 12-16 illustrate a needle hub attached to the needle. In addition, the needle carrier is described in greater detail in connection with the first embodiment, in the description on page 8, lines 10-21. Accordingly, claim 23 should not have been withdrawn from consideration.

Claim 36

Claim 36 recites that the biasing element is a compression spring disposed between the distal end of the barrel and the needle. The description for the elected embodiment specifically states that the spring circumscribes the needle and is compressed against the interior of the barrel. See page 22 lines 8-10. This arrangement is also illustrated in Figs. 12-13. Since the features of claim 36 are described in the application, claim 36 should not have been withdrawn.

Claim 37

Claim 37 recites that the needle retainer comprises a pair of forward windows in the barrel and a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage the forward windows. Figures 12-16 show a needle retainer comprising a pair of windows at the forward end of the barrel and a pair of tines. In addition, on page 22 the application states that the needle retainer for the embodiment in Figures 12-16 is substantially similar to the needle retainer in the first embodiment, which is described in greater detail on page 9 lines 6-19. This portion of the description more clearly describes the features in claim 37. Since the application discloses the features of claim 37 for the elected species, claim 37 should not have been withdrawn.

In light of the foregoing, Applicants request that the Examiner reconsider the withdrawal of claims 5, 13, 23, 27, 30 and 35-37. In addition, although the

discussion indicates that the features of these claims are disclosed in the application in connection with the elected species, there is no intention to limit the claimed features to the embodiments described in the application and discussed above.

§112 Rejection of Claims

Applicants' undersigned attorney is unclear about the basis of the rejection under §112. The Official Action states that the disclosure is not enabling for the fluid flow controller and the needle carrier in claims 1 and 2, which are critical or essential to the practice of the invention, but not included in the claims. In other words, the Official Action states that the fluid flow controller and the needle carrier are recited in the claims, but the claims are not enabled because these two elements are necessary elements that are not recited in the claims. How can the elements be recited in a claim, and not included in the claim at the same time?

Further, the Official Action states that there is no such language in the specification, so the examiner is not sure what the applicant is trying to claim. However, there is no requirement that the language used in the claims be the exact same as the language in the detailed description. See MPEP §2163.02 (stating that "the subject matter of the claim need not be described literally (i.e. using the same terms or in haec verba)").

The terms needle carrier and fluid flow controller are quite clear terms that correspond to structural elements clearly illustrated and described in the detailed description. For instance, the application shows and describes a needle hub 31 to which the needle is fixedly attached. The needle hub is illustrated in each of the embodiments. How does the needle hub operate? It carries the needle (i.e. a needle carrier). In addition, a needle carrier is an element that is frequently used in the art to describe some type of element that is used to carry a needle. Accordingly, the term "needle carrier" as used in the claims is clear and definite as required by §112.

Similarly, the term "fluid flow controller" as used in the claims is clear. The fluid flow controller is just that, an element that controls the flow of fluid. The application describes and illustrates various structural elements that control the flow of fluid. For instance, in the elected species, the fluid flow controller is described as a fluid passage in the form of a bubble in the cartridge that cooperates with a mid seal to control the flow of fluid between the first and second chambers. Since the term fluid flow controller is clear and the structure corresponding to a fluid flow controller is illustrated and described in the specification, the term is clear and definite as required by §112 even though the exact words "fluid flow controller" are not used in the specification.

For similar reasons, Applicants request that the Examiner reconsider the objection to the specification for the terms fluid flow controller and needle carrier. The

terms are clear and there is no need for the claim terms to be used verbatim in the specification.

Lavi 6,723,068

The Examiner rejected claims 1-4, 6-10, 16, 19, 20, 22, 24, 25, 28, 31-33 and 48-40 as anticipated by Lavi 6,723,068. However, as discussed below, the device in Lavi operates quite differently than Applicants' device, and there are numerous differences between the claims and Lavi.

Lavi discloses an injector that operates in connection with two separate cartridges 116 and 102. The first cartridge 102 includes a dried powder. The second cartridge contains a diluent for re-constituting the dried powder in the first cartridge. Both cartridge mount onto a housing 304-1.

A U-shaped needle 131 is attached to a plunger 174 that moves in and out through the housing 304-1. An injection is provided by placing the housing against the skin of a patient and pushing the plunger forwardly in the housing. Pushing on the plunger displaces the needle forwardly so that a forward sharpened tip of the needle projects out from the housing and into a patient. At the same time, pushing on the plunger 174 causes the rearward end of the needle to pierce a seal 170, allowing fluid to flow through a passage and into the needle. Compressed air or gas in the first cartridge 102 cause the mixed fluid to flow out of the first cartridge and into the patient.

Referring to claim 1, there are numerous features that Lavi does not teach or suggest. For instance, Lavi does not teach a plunger slidably displaceable within the cartridge. Instead, in Lavi, the operation of the plunger is remote from the cartridges; the plunger simply displaces the U-shaped needle. Further, Lavi does not teach "axially advancing the plunger within the first chamber [to] advance the first substance . . . " as recited in claim 1. Still further, Lavi does not teach or suggest "continued advancement of the plunge and cartridge relative to the barrel after the mixture is expelled" causing actuation of the needle retainer to release the needle.

In light of the distinction discussed above, and other differences between Lavi and claim 1, Lavi noes not anticipate claim 1. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 1 over Lavi. For similar reasons, Lavi does not anticipate claim 22.

With regard to claim 40, Lavi does not teach or suggest a needle retainer for releasably retaining the needle in the extended position. In fact the Official Action does not even mention a needle retainer when discussing the rejection of claim 40 over Lavi. Of course the fact that Lavi does not teach or suggest a needle retainer is apparent from the fact that Lavi uses a needle that is retained in a retracted position and is then manually advanced and held forwardly by pressing on the plunger 174. Since Lavi does not teach or suggest a needle retainer, Lavi does not anticipate claim 40.

Hurscham 3,946,732

The Examiner rejected claims 1-4, 6-10, 16, 19, 20 and 40 as anticipated by Hurscham. However, Hurscham does not teach or suggest numerous features of the claims because Hurscham is directed to a device that operates quite differently from Applicants' device.

One significant difference between Hurscham and Applicants' device is that the Hurscham device is not a safety product. Hurscham utilizes a fixed needle that is neither retracted or shielded in any way after use. Accordingly, Hurscham does not include a needle operable between an extended position and a retracted position, a biasing element biasing the needle toward the retracted position and a needle retainer releasably retaining the needle against the bias of the biasing element. For these and other reasons, Hurscham does not anticipate claims 1, 22 and 40.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **THREE** months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

May 17, 2005
Date of Certificate

_____
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